



Medical Necessity Criteria for Newer Sedative Hypnotic Agents

Drug Class – Newer Sedative Hypnotic Agents

Background – After evaluating the relative clinical and cost effectiveness of the Newer Sedative Hypnotic Agents, the DoD P&T Committee recommended that the following medications be designated as non-formulary under the Uniform Formulary. This recommendation has been approved by the Director, TMA.

- Rozerem (ramelteon)
- Edluar (zolpidem sublingual, SL)
- Zolpimist (zolpidem oral spray)

Patients currently using a non-formulary agent may wish to ask their doctor to consider a formulary alternative.

Special Notes:

1. Active duty cost share always \$0 in all points of service for all three tiers; Active duty cost share always \$0 in all points of service for all three tiers; TRICARE does not cover non-formulary medications for active duty service members unless they are determined to be medically necessary.
2. MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.
3. Step therapy/prior authorization (PA) requirements apply to all drugs in this class except zolpidem immediate release (Ambien) and Sonata (zaleplon). The medical necessity form may NOT be used to meet PA requirements.

Medical Necessity Criteria for Newer Sedative Hypnotic Agents

The non-formulary cost share for Rozerem or Edluar may be reduced to the formulary cost share if the patient meets the following criteria:

1. The patient has had an inadequate response to, been unable to tolerate due to adverse effects, or has contraindications to the formulary agents (e.g., hypersensitivity, aberrant behaviors, or intolerable rebound insomnia).
2. For Edluar or Zolpimist, the patient is unable to swallow or has swallowing difficulties.
3. For Rozerem, the patient requires a non-controlled agent due to potential for abuse and cannot take Silenor (doxepin).

Criteria approved through the DOD P&T Committee process May 2012

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TRICARE Pharmacy Program Medical Necessity Form for Edluar, Rozerem, and Zolpimist



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This form applies to the TRICARE Pharmacy Program (TPHarm). The medical necessity criteria outlined on this form also apply at Military Treatment Facilities (MTFs). The form must be completed and signed by the prescriber.

- **Newer sedative hypnotic agents on the DoD Uniform Formulary include zolpidem immediate- and extended-release tablet (Ambien, Ambien CR), zaleplon (Sonata), Intermezzo (zolpidem sublingual tablet), Lunesta (eszopiclone), and Silenor (doxepin).** Edluar (zolpidem sublingual tablet), Rozerem (ramelteon), and Zolpimist (zolpidem oral spray) are non-formulary, but available to most beneficiaries at the non-formulary cost share. **Please note that prior authorization (PA) requirements apply to all drugs in this class EXCEPT zolpidem immediate-release (Ambien) and zaleplon (Sonata), which do not require PA.** PA forms are available on the TRICARE Pharmacy website at: http://pec.ha.osd.mil/forms_criteria.php. This Medical Necessity form may **NOT** be used to meet PA requirements.
- You do NOT need to complete this form in order for non-Active duty beneficiaries (spouses, dependents, and retirees) to obtain non-formulary medications at the non-formulary cost share. The purpose of this form is to provide information that will be used to determine if the use of a non-formulary medication is medically necessary. If a non-formulary medication is determined to be medically necessary, non-Active duty beneficiaries may obtain it at the formulary cost share.
- Active duty service members may not fill prescriptions for a non-formulary medication unless it is determined to be medically necessary. There is no cost share for active duty service members at any DoD pharmacy point of service.

MAIL ORDER and RETAIL	<ul style="list-style-type: none">• The provider may call: 1-866-684-4488 or the completed form may be faxed to: 1-866-684-4477• The patient may attach the completed form to the prescription and mail it to: Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954 or email the form only to: TpharmPA@express-scripts.com	MTF	<ul style="list-style-type: none">• Non-formulary medications are available at MTFs only if both of the following are met:<ul style="list-style-type: none">▪ The prescription is written by a military provider or, at the discretion of the MTF, a civilian provider to whom the patient was referred by the MTF.▪ The non-formulary medication is determined to be medically necessary.• Please contact your local MTF for more information. There are no cost shares at MTFs.
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Step 1 Please complete patient and physician information (please print):

1	Patient Name: _____	Physician Name: _____
	Address: _____	Address: _____
	Sponsor ID # _____	Phone #: _____
	Date of Birth: _____	Secure Fax #: _____

Step 2 1. Please indicate which medication is being prescribed:

Edluar (zolpidem sublingual tablet) _____ Zolpimist (zolpidem oral spray) _____
Rozerem (ramelteon) _____

2. Please explain why the patient cannot be treated with the formulary medications. Circle a reason code if applicable. You **MUST** supply a specific written clinical explanation as to why each of the formulary medications would be unacceptable.

Formulary Medication	Reason	Clinical Explanation
Zolpidem immediate-release (Ambien)	1 2 3 4 5	
Zaleplon (Sonata)	1 2 3 4 5	

Acceptable clinical reasons for not using a formulary medication are:

1. Patient has tried the formulary medication and had an inadequate response.
2. Patient has been unable to tolerate the formulary medication due to adverse effect.
3. Use of the formulary medication is contraindicated (e.g., due to hypersensitivity, aberrant behaviors, intolerable rebound insomnia).
4. **(Rozerem only)** Patient requires a non-controlled agent due to potential for abuse AND cannot take doxepin (Silenor). [Explain why Silenor would not be an option.]
5. **(Edluar and Zolpimist only)** The patient is unable to swallow or has difficulty swallowing.

Step 3 I certify the above is correct and accurate to the best of my knowledge. Please sign and date:

3	_____ Prescriber Signature	_____ Date
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[04 January 2013]